The Ethics of Food Production and Regulation of "Misbranding"

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Abstract

As consumers have become more conscious of the ethical implications of food choices, the food industry has capitalized on our concern by introducing labels that appeal to our moral sensibilities. Labels such as "free range" and "cage free" influence the purchasing decisions of consumers because these labels suggest production methods with fewer harmful ethical implications, whether with regard to animal welfare or environmental sustainability. In response to consumer demand for more ethical food choices, production method labeling has become widespread. Nevertheless—and despite pervasive regulation of other types of food labeling—oversight of production methods claims is virtually nonexistent. Thus, consumers rely on labels such as "free range" to make purchasing decisions, without knowing what "free range" really means. The misbranding provisions of FDA's and USDA's authorizing statutes grant the agencies the ability to prohibit claims that are "false and misleading in any particular." Under these provisions, the agencies could regulate production method claims to protect American consumers who are concerned about the ethical implications of what they eat. This paper explores the challenges to using the misbranding provision to regulate labeling of production methods—and how the provision might be used to protect consumers from false and misleading production method claims.

Ethical Concerns about Food Production

The nationwide outrage that resulted in the 1906 passage of the first federal food and drug law and meat inspection act was not about the confinement of egg-laying hens or the treatment of veal calves. It wasn't about the number of calories or the amount of sugar in a food product. Instead, Americans were concerned primarily with the disturbingly unsanitary conditions in which their food was being produced—conditions made known by the publication

of Upton Sinclair's *The Jungle*, which documented the deplorable conditions of Chicago's meat packing plants. The public failed to sympathize with the workers of the meatpacking industry and adopt the socialist cause, as Sinclair—an ardent critic of capitalism—had hoped they would. But Sinclair's novel did elicit public outrage when it exposed the meat packing industry's unsanitary production methods, which included selling rotten, diseased meat to unsuspecting consumers.[1] Thus, the first federal food and drug law resulted from concerns about food safety.

Concerns about our food supply today are much different. Of course, Americans are still concerned about food safety, though now we believe that the United States Department of Agriculture ("USDA") will ensure that our meat is neither rotten nor diseased.[2] But we want more than a guarantee that our food isn't rotten. We also want to know whether our food is healthy, including the caloric content, amount of sugar and sodium, and the quantity of vitamins in contains. Just as the federal food and drug act of 1906 reflected the public's concern with food safety, the National Labeling and Education Act ("NL&E Act") of 1990 reflects our concern with the nutritional value of our foods.[3] Empowering consumers with the knowledge contained on the Nutrition Facts label, the Food and Drug Administration ("FDA") enables us to

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[1] Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food Drug Cosmetic L.J. 2 (1984), reprinted in Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 10 (3d ed. 2007).

[2] Meat was also inspected at the turn of the twentieth century, when Sinclair wrote his expose of the meat packing industry. (There was no federal regulation at that time, but states regulated food production prior to the enactment of federal laws.) Indeed, *The Jungle* included stories about collusion between managers of the meat packing plants and supposed regulators, who would deliberately allow unsafe meat to be packaged for sale.

[3] *See* Peter Barton Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, *In* Ralph Shapiro, ed., Nutrition Labeling Handbook, Ch.1 (1995), reprinted in Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 209 (3d ed. 2007).

make informed decisions about the foods we consume. But while current labeling requirements enable consumers to choose between foods based on nutritional value, they don't enable us to make decisions based on ethical concerns about a food's production.

Yet consumers today are concerned about more than food safety and nutritional content. As we've become aware of the ethical implications of modern-day food production, consumers have sought foods produced by methods with fewer harmful consequences for animal welfare and the environment. Nearly all of the 10 billion animals that are raised for food in the United States each year are raised on factory farms under inhumane conditions, including confinement in filthy cages that are so small that the animals are unable to walk or turn around.[4] Factory farming also has disastrous environmental impacts, from significantly contributing to climate change to creating huge amounts of manure that pollute our soil, water, and air.[5] We've also become aware of the social implications of what we eat; for example, many consumers object to the use of biotechnology because it increases the "dependence of farmers throughout the world (but notably in less developed countries) on a limited number of multinational actors."[6]

Concern about the ethical implications of our food supply is obvious to anyone who has perused the aisles of a supermarket. Food labels inform us that certain brands of eggs are "cage free" or "free range," that our coffee is "fair trade," and that our milk was produced by cows that were not shot up with genetically-engineered growth hormones. Clearly, food producers are well

[4] Official Food, Inc. Movie Site, "Hungry for Change? About the Issues," http://www.foodincmovie.com/about-the-issues.php. Website accessed March 10, 2010.

[5] Humane Society of the United States website, "Factory Farming: Environmental Impact," http://www.humanesociety.org/issues/environment/. Website accessed March 10, 2010.

[6] Hub Zwart, *A Short History of Food Politics*, Journal of Agricultural and Environmental Ethics 12: 113-126, 2000.

aware of consumer concerns about the ethical production of food. Indeed, even supermarket chains have responded to consumer demands. In 2005, Whole Foods Market and Wild Oats announced that they would no longer sell eggs from caged hens.[7] More recently, Wal-Mart announced that its private label ("Great Value") eggs are all cage-free.[8]

The wide array of food labels targeting consumers who are concerned about ethical food production methods suggests that food producers know many consumers will choose products because they are less harmful to animal welfare or the environment. Indeed, many consumers will pay a premium for these products, as the cost of a dozen "cage-free" eggs is invariably more expensive than a dozen eggs produced by caged hens. Undoubtedly, these labels help consumers make food choices based on their ethical concerns—just as nutrition labeling helps consumers make healthy food choices. In a world in which we are so far removed from the production of our food supply, labels are our only means of obtaining the information we need to make good decisions. Because food producers respond to consumer demand, having information about food production methods not only enables consumers to make personal choices about what we eat— it also enables us to "effect a change in the way food is actually produced."[9]

Production methods and the current regulation of food labeling

Despite that labeling of food production methods has become so widespread, regulation of this labeling is essentially nonexistent. Thus, food producers can capitalize on our ethical

[7] "Wild Oats and Whole Foods Sow Compassion with Cage-Free Egg Policies," Humane Society of the United States website, June 3, 2005, http://www.hsus.org/farm/camp/nbe/wildoats/wild_oats.html.

[8] "Wal-Mart: Private Label Eggs All Cage-Free," Humane Society of the United States website, February 18, 2010, http://www.humanesociety.org/news/press_releases/2010/02/wal-mart_021810.html.

[9] Hub Zwart, *A Short History of Food Politics*, Journal of Agricultural and Environmental Ethics 12: 113-126, 2000.

concerns about the food we eat with very little oversight of their claims. The FDA's regulation of food labeling focuses primarily on the ingredients in a food product and its nutritional content. Section 403 of the federal Food, Drug, and Cosmetic Act ("FD&C Act") includes both affirmative requirements for labeling and prohibitions against certain representations that are voluntarily included on a food label. For example, the FD&C Act requires disclosure of information such as the name, ingredients and nutrient content of the food. Additionally, it prohibits statements on labels that are "false and misleading in any particular."[10] In 1990, the NL&E Act gave the FDA express authority to regulate nutrient content claims and disease prevention claims.[11] It requires FDA to define commonly-used nutrient descriptors—such as "high fiber," "low fat" and "reduced cholesterol"—and to review disease prevention claims to determine their suitability for food labeling.[12] Thus, FDA's regulation of food labeling pertains primarily to information about the content and nutritional value of foods—and does not include requirements specific to regulating food production claims.

The United States Department of Agriculture, on the other hand, does specifically consider food production claims. In 2002, USDA proposed regulations that would establish minimum requirements for commonly-used production claims, relating to production methods such as antibiotic use and confinement standards.[13] However, given that USDA is tasked not

[10] Federal Food, Drug, and Cosmetic Act, §403(a)(1), 21 U.S.C. §343.

[11] *See* Peter Barton Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, *In* Ralph Shapiro, ed., Nutrition Labeling Handbook, Ch.1 (1995), reprinted in Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 209 (3d ed. 2007).

[12] *Id.*

[13] "United States Standards for Livestock and Meat Marketing Claims," Agricultural Marketing Service, USDA, 67 Federal Register 250 (30 December 2002), pp.75882-79556.

only with protecting consumers, but also with promoting the nation's agricultural products, we might wonder whether USDA minimum requirements for production claims would meet the ethical standards of consumers who rely on that information to distinguish between products.[14] The livestock industry's definition of "free range" or "cage free," for example, might not comport with the concerned consumer's definition of the same production claim. Indeed, while the proposed standard suggests that "free range" means livestock having "continuous and unconfined access to pasture throughout their life cycle," the USDA's website defines it much differently—as simply livestock that has "access to the outside."[15] Animal welfare organizations have strongly criticized the ability of livestock producers to label their products as "free range" or "cage free," despite that the animals have little, if any, access to the outside and spend their entire lives in filthy, cramped sheds devoid of sunlight.[16] Consumers who buy eggs laid by purportedly "free range" or "cage free" hens buy these products because they believe the animals are humanely treated and live healthy lives. They certainly don't expect what USDA's definitions allow.

Toward regulation of food production claims - §403(a)'s "misbranding" provision

Neither the FD&C Act nor the Federal Meat Inspection Act ("FMIA"), which give FDA and USDA authority to regulate labeling of food products, refers to regulation of production

[14] The proposed regulations referred to above, for example, note that their purpose is to enable meat producers to promote their products by credibly (through USDA certification) distinguishing them from those of their competitors. *See id.*

[15] *See id. See also* "Fact Sheets: Meat and Poultry Labeling Terns," Food Safety and Inspection Service website, http://www.fsis.usda.gov/Fact_Sheets/Meat_&_Poultry_Labeling_Terms/index.asp.

[16] "'Free-Range' Poultry and Eggs: Not All They're Cracked Up To Be," United Poultry Concerns website, http://www.upc-online.org/freerange.html. Website accessed March 10, 2010.

method claims on food labeling. Certainly, Congress could pass legislation requiring FDA or USDA to regulate labels such as "cage free," just as Congress now requires FDA to review nutrient content claims and disease prevention claims.[17] Such legislation could compel the agencies to define commonly-used production claims and ensure that food producers labeling their products with those claims complied with the established definitions.[18] Production method labeling legislation could also simply give FDA and USDA the authority to regulate production method claims, without requiring that the agencies do so.

Even without legislation, however, FDA and USDA could regulate production method claims under their current authorizing statutes. Specifically, the "misbranding" provision, which is identical in both the FD&C Act and the FMIA, could be used to ensure that production method claims are not misleading to consumers who make purchasing decisions based on ethical considerations. The misbranding provision prohibits labels that are "false and misleading in any particular," giving the agencies wide latitude in determining whether a food product has been misbranded. The remainder of this paper will explore the challenges to using the misbranding provision to regulate production claim methods—and how the provision might be used to regulate such claims.

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[17] *See* Peter Barton Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, *In* Ralph Shapiro, ed., Nutrition Labeling Handbook, Ch.1 (1995), reprinted in Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 209 (3d ed. 2007).

[18] Of course, how such production method claims are defined is important as well, as we see with the case of USDA's current use of the "free range" definition—certainly consumers who buy products labeled with this claim think it means more than "access to the outside."

Using misbranding to regulate food production claims

The Food, Drug and Cosmetic Act and the Federal Meat Inspection Act prohibit the misbranding of food in interstate commerce.[19] A food is misbranded if (among other reasons) its label is "false or misleading in any particular."[20] The FD&C Act also further clarifies that labeling can be false or misleading based not only on the representations made, but also if "the labeling…fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling…relates under the conditions of use prescribed in the labeling…or under such conditions of use as are customary or usual."[21] Thus, labeling can be deemed false or misleading under the FD&C Act in two different ways. First, a representation on the label could be determined to be "false or misleading." Alternatively, FDA could determine that a food is misbranded based on what the label *doesn't say*—if the missing information is deemed "material." Whether production claims can be regulated under the misbranding provision depends upon whether voluntarily-made labeling representations—such as "free range"—are false and misleading, or alternatively, whether failing to inform consumers of production methods is considered a failure to reveal material facts.

"False and misleading in any particular"

Although FDA and USDA have not historically used the prohibition against misbranding to regulate production method claims, they could do so under the FD&C Act and the FMIA. Indeed, these statutes give the agencies broad authority to determine whether labels are false and

[19] Federal Food, Drug, and Cosmetic Act, §301(b), 21 U.S.C. §331. Federal Meat Inspection Act, §610(c).

[20] Federal Food, Drug, and Cosmetic Act, §403(a)(1), 21 U.S.C. §343. Federal Meat Inspection Act, §601(n)(1).

[21] Federal Food, Drug, and Cosmetic Act, §201(n), 21 U.S.C. §321.

misleading. The statutes themselves express this broad authority, as the agencies can determine that misbranding has occurred if the label is "false or misleading *in any particular*."[22] This language suggests Congressional intent to enable the agencies to develop strong misbranding standards. Courts have upheld that broad grant of discretion, reasoning that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public."[23] Courts have also rejected the argument that the misbranding standard requires that the false or misleading statement be "material," reaffirming the wide latitude given to the agencies enforcing it.[24]

The meaning of "false and misleading," however, has evolved dramatically during the last century. Although the federal food and drug act of 1906 included a misbranding provision, the courts were left to define what constitutes false and misleading labeling. Early decisions established that a literally true statement could violate the Act, since "[d]eception may result from the use of statements not technically false or which may be literally true."[25] Yet even if we accept that deception can result from technically true statements, we must also answer the question: To whom must the statement be deceiving? Who must be misled by the labeling in question for it to be deemed "false or misleading" and, thus, prohibited under the misbranding provision? One of the first courts to address this issue determined that whether a label is misleading should be judged based on the consumer's first impression, despite whether a more

[22] Federal Food, Drug, and Cosmetic Act, §403(a)(1), 21 U.S.C. §343. Federal Meat Inspection Act, §601(n)(1).

[23] U.S. v. An Article of Drug…Bacto-Unidisk, 394 U.S. 784, 798 (1969).

[24] U.S. v. Jorgensen, 144 F.3d 550, 559 (1998). The court also rejected that the argument that the "in any particular" language of the misbranding provision "violates due process because it is overly broad and vague."

[25] U.S. v. Ninety-Five Barrels, More or Less, Alleged Apple Cider Vinegar, 265 U.S. 438, 443 (1924).

deliberate reading would correct the initial impression. Average consumers, the court reasoned, do not carefully analyze labels; instead they rely upon "a hasty glance or cursory examination."[26]

Most recently, two different standards have been used to evaluate whether a label is false or misleading: the "IUC" standard and the "reasonable consumer" standard. The IUC standard, developed by courts after the passage of the FD&C Act in 1938, evaluates whether a label is misleading in reference to "the ignorant, the unthinking and the credulous."[27] The misbranding provision was construed broadly, making it irrelevant whether the reasonable consumer would understand the labeling.[28] The purpose of the Act is to protect the public, the courts reasoned, and the public includes "the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze."[29] The IUC standard thus attempts to protect all consumers, giving FDA and USDA wide latitude to deem labels false or misleading.

In 2002, FDA clarified that it would use the "reasonable consumer" standard in evaluating whether labels are false or misleading.[30] This decision was an attempt to "rationalize the legal and regulatory environment for food promotion," given that the Federal Trade Commission—which regulates misleading claims in food advertising—uses the reasonable consumer standard. This standard, according to FDA, "more accurately reflects that consumers

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[26] U.S. v. Ten Barrels of Vinegar, 186 F. 399, 401 (D.C.Wis.1911).

[27] *See* U.S. v. Strauss, 999 F.2d 692, 696 (2nd Cir. 1993).

[28] *Id.*

[29] U.S. v. El-O-Pathic Pharmacy, 192 F.2d 62, 75 (C.A.9 1951).

[30] "Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability," Food and Drug Administration, HHS, 67 Federal Register 245 (20 December 2002), pp. 78002-78004.

are active partners in their own health care who behave in health promoting ways when they are given accurate health information."[31] FDA's decision also rested on first amendment case law precluding regulation of "the content of promotional communication so that is contains only information that will be appropriate for a vulnerable or unusually credulous audience."[32] This suggests that the IUC standard may itself be constitutionally impermissible in that it seeks to protect all consumers, including those who are thought to be particularly vulnerable to potentially misleading labeling claims.

Notwithstanding potential constitutional infirmities, the IUC standard and reasonable consumer standard can be analyzed by how well they enable FDA to effectuate the consumer protection purpose of the FD&C Act. As earlier court decisions noted, the remedial nature of the legislation suggests that it should be read broadly to give the agency maximum ability to protect consumers.[33] In this sense, the IUC standard seems superior; FDA is tasked with protecting consumers as a whole, not just those consumers who carefully analyze labels. Determining which standard is more appropriate, however, also depends upon the practical implications of choosing one standard over another. It is questionable whether FDA would even reach different conclusions about whether a label is misleading by using one standard rather than the other.

A new standard for evaluating "false and misleading" labels?

In the context of regulating production method claims, however, neither the IUC standard nor the reasonable consumer standard best protects those consumers who make purchasing decisions based on the ethical implications of what they eat. Certainly, a consumer who is

[31] *Id.* at 78004.

[32] *Id*., citing Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 73-74 (1983).

[33] U.S. v. Article of Drug…Bacto-Unidisk, 394 U.S. 784, 798 (1969).

searching for "free range" eggs would not fall into the category of consumers who do not carefully analyze labels, but instead rely upon "a hasty glance or cursory examination."[34] Indeed, for these consumers—who are specifically looking for foods produced, for example, in humane ways—the IUC standard seems not to apply at all. The reasonable consumer standard, on the other hand, could apply to production method claims—for example, "cage free" would be a misleading label if the eggs were produced by hens that were more severely confined that what the reasonable consumer would consider to be "cage free."

The reasonable consumer standard, however, leaves consumers who make purchasing decisions based on ethical considerations insufficiently protected from misleading claims; thus, the consumer protection purpose of the FD&C Act is not realized when production method claims are evaluated using this standard. For example, the "reasonable consumer" might believe that "cage free" means simply that the chickens were not caged. If so, the deplorable conditions in which hens that lay "cage free" eggs are kept—thousands of birds crammed so tightly into a shed devoid of sunlight that they can barely move[35]—might be neither false nor misleading. Yet it is virtually unquestionable that consumers who buy "cage free" eggs, and pay a premium in doing so, choose that product because they believe—whether "reasonably" or not—that the eggs were produced using hens that were humanely treated. Consumers who care about the humane treatment of hens would not consider the conditions under which "cage free" hens are confined to be humane—yet they buy these eggs because they believe the hens are humanely treated.

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[34] United States v. Ninety-Five Barrels, More or Less, Alleged Apple Cider Vinegar, 265 U.S. 438, 401 (1924).

[35] "'Free-Range' Poultry and Eggs: Not All They're Cracked Up To Be," United Poultry Concerns website, http://www.upc-online.org/freerange.html. Website accessed March 10, 2010.

Otherwise, why would these consumers be willing to pay a premium for the product labeled "cage free"?

Furthermore, judging whether a production method claim is misleading under the reasonable consumer standard would allow the food industry to capitalize on the ethical concerns of consumers without delivering products that actually respond to those concerns. As noted above, consumers are charged a premium for products labeled "cage free," "free range," or "humanely raised." These consumers are willing to pay this premium only because they believe they are purchasing products produced with fewer harmful consequences to the animals used in their production. The extra cost is justified for these consumers because they recognize that raising animals humanely is more expensive for food producers. However, producing "cage free" eggs may not actually be as expensive as consumers believe, given that the hens may simply be crammed into a windowless shed. Thus, consumers are not only being duped into buying products that they wrongly believe were produced in a humane way—they are also being duped into paying more for those products.

Because neither the IUC standard nor the reasonable consumer standard would effectively address the problem of misleading production method claims, a new standard should be used when evaluating whether such claims are "false or misleading." In the context of production method claims, consumers often choose products based on their ethical implications and—as we've seen—the food industry capitalizes on this concern by labeling their products with these claims. Thus, the consumers who need FDA protection in this context are the consumers who are buying these products based on what they believe the claims, such as "humanely raised" or "cage free," to mean. It is irrelevant what other consumers—who are not concerned about whether their eggs are "cage free" and, thus, do not seek out these products—

believe the production method claims mean. Thus, a more effective standard for evaluating whether production method claims are misleading might be called the "purchasing consumer" standard. Such a standard would judge production method claims in reference to what the consumer purchasing the product—who undoubtedly cares about the production method, given that she is willing to pay a premium for such products—believes that it means. Thus, if the "purchasing consumer" believes "cage free" means the hens that produce the eggs are humanely treated—and, therefore, chooses to buy those eggs over others—an egg producer would violate the misbranding prohibition if the hens were actually kept crammed into filthy, windowless sheds with no room to move.[36]

The regulation of production method claims may seem to be an overreach of FDA and USDA's authority under the FD&C Act and the FMIA. The mission of these agencies, some might argue, is simply to protect the health and safety of American consumers. However, FDA and USDA have broad authority under the misbranding provisions of their statutes to protect consumers from labeling claims that are "false and misleading in any particular."[37] Moreover, an analogy could be made to the economic adulteration prohibition in the FD&C Act, which provides that a food is adulterated if "any substance has been added thereto or mixed or packed therewith so as to…make it appear better or of greater value than it is."[38] The economic adulteration provision is intended not to protect the health and safety of consumers, but instead to

[36] Although there might be disagreement about what constitutes "humane" treatment, certainly the current conditions in which most animals raised for food are kept would not qualify as humane. FDA or USDA regulations could identify an expert organization, such as the Humane Society of the United States, to determine what constitutes such "humane" treatment. The accuracy of production method claims could then be based on such standards.

[37] Federal Food, Drug, and Cosmetic Act, §403(a)(1), 21 U.S.C. §343. Federal Meat Inspection Act, §601(n)(1).

[38] Federal Food, Drug, and Cosmetic Act, §4032(b), 21 U.S.C. §342.

protect their wallets. Although the provision focuses on the addition of cheap ingredients (or omission of valuable ingredients)—and production method claims focus on the way in which the food was produced, rather than its ingredients—both could be said to protect consumer pocketbooks.

Thus, FDA or USDA could regulate voluntarily-made production method claims by assessing whether the claims are "false and misleading in any particular" and, therefore, violate the misbranding provisions of the FD&C Act and the FMIA. In doing so, however, the agencies should abandon the "reasonable consumer" standard and adopt a standard through which claims are assessed based on how the consumer who seeks out and purchases the product assesses them—the "purchasing consumer" standard. This standard would ensure that consumers who make purchases based on the ethical implications of what they eat are not duped into buying products that do not meet their ethical standards—and paying more for those products.

"False and misleading" due to failure to reveal material facts

The misbranding provision of the Food, Drug, and Cosmetic Act not only prohibits labeling that is misleading due to representations made on the label; rather, the statute also defines misbranding based on what is missing from the label. In addition to being misbranded due to a false or misleading representation, a food can be misbranded if "the labeling…fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling…relates under the conditions of use prescribed in the labeling…thereof or under such conditions of use as are customary or usual."[39] Evaluating whether a label is misleading based solely on representations made enables FDA to judge labels based only on what food producers voluntarily include on labels. This

[39] Food, Drug, and Cosmetic Act, §201(n), 21 U.S.C. §343.

provision, however, also enables FDA to determine that a product is misbranded even if the food producer makes no affirmative claims on the label.

The authority to deem a product misbranded based on failure to reveal material facts potentially expands FDA's authority over labeling in a significant way. Not only can the agency judge labeling representations and claims; it can also determine that failing to include important information on a label violates the FD&C Act. Thus, the agency isn't limited only to evaluating what food producers claim through labeling, but can also impose requirements to include certain information on labels. Moreover, this provision enables FDA to establish labeling requirements through rulemaking, rather than judging labels on a case by case basis through adjudication.[40] Despite these advantages, FDA has interpreted this provision such that its application to production method claims is uncertain.

"Failure to reveal facts material in light of such representations"

One way that FDA is authorized under §201(n) to determine that a label is misleading is by evaluating the extent to which the label "fails to reveal facts material in light of such representations." Thus, if the food producer fails to disclose a fact that is material based on what it *does* disclose on the label, it violates the misbranding provision of the FD&C Act. Clearly, FDA's authority under this provision to determine a label is misleading depends upon the interpretation of the meaning of "material." Because Congress did not define materiality in the FD&C Act, the agency has broad discretion to determine what constitutes a material fact.[41]

[40] *See* American Frozen Food Institute v. Mathews, 413 F.Supp. 548, 552 (D.C.1976), noting that "[t]he cases are legion in which Courts have recognized the preference of substantive rulemaking by an agency over the time consuming and often unfair process of case by case adjudication."

[41] *See* Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166, 178 (D.C.2000).

In an early case discussing materiality, a district court upheld FDA regulations that required producers of seafood cocktails to include percentage of ingredient-labeling on the product packaging.[42] FDA determined that, under §201(n), the percentage of the seafood cocktail that was actually seafood was a material fact, the failure of which to disclose resulted in misleading labeling. The regulations required that the amount of the "characterizing ingredient" (in this case, seafood) be disclosed when "the proportion of [the] ingredient…has a material bearing on price or consumer acceptance."[43] The court found the substantial consumer interest in knowing the percentage of seafood ingredient to be indicative of the materiality of this information.[44] Thus, both the price and the consumer acceptance of a product were treated as material facts with regard to whether information absent from a label was required to be disclosed.

American Frozen Food Institute also noted the importance of providing consumers with "sufficient information on the labels of food products so that reasoned and informed shopping decisions could be made."[45] Indeed, this is the purpose of food labeling requirements generally. Moreover, the court regarded the ability of consumers to make choices between food products to be relevant in determining materiality, citing that "several consumers [found disclosure to be] a

[42] American Frozen Food Institute v. Mathews, 413 F.Supp. 548 (D.C.1976).

[43] *Id.* at 554.

[44] *Id.*, noting that "[v]irtually all of the consumer response heartily supported the general principle proposed, and several consumers indicated express approval of disclosure of percentage of ingredients for seafood cocktails as a necessary device for comparative food shopping."

[45] *Id.* at 551.

necessary device for comparative food shopping."[46] The importance of consumer knowledge, therefore, is that it enables us to make informed purchasing decisions and compare products when making such decisions.

If §201(n) gives FDA the authority to promulgate regulations requiring percentage of ingredient-labeling requirements, it might also give FDA the authority to require production method labeling in certain circumstances. In both cases, there is no risk to consumer health or safety; rather, the concern is consumer interest in having the information and, thus, ability to make informed purchasing decisions. Just as the consumer desire to know the percentage of seafood content in *American Frozen Food Institute* was the foundation for materiality,[47] the consumer desire to know the animal welfare or environmental consequences of food choices could be a "material fact" that must be disclosed. Certainly, the proliferation of voluntarily-made production method claims—such as "cage free," "humanely raised" and "free range"—suggests that food producers are aware of a strong consumer desire to have such information. Further, *American Frozen Food Institute* noted the importance of giving consumers the information they need to compare food products[48]—and the whole purpose of production method claims is to enable consumers to choose products that reflect their ethical sensibilities. Thus, FDA could use this prong of §201(n) to mandate production method disclosure, rather than simply to regulate voluntarily-made production method claims.

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[46] *Id.* at 554.

[47] *Id.*

[48] *Id.*

Under this prong of §201(n), however, the FD&C Act is violated only if the label "fails to reveal facts material *in light of such representations*" (emphasis added).[49] In other words, the seafood cocktail producers had to include the percentage of ingredient-labeling because the label already claimed the product was seafood—in other words, the percentage of seafood was required to be disclosed because it was material "in light of" the representation that the product was indeed "seafood." Thus, to mandate production method labeling under this prong, the label must fail to disclose the production method "in light of" some other representation made on the label.

It may seem unlikely that labels without production method claims would make representations that would establish materiality of the facts not disclosed. However, given the extent to which representations about production method claims are made today, such representations may be quite common. For example, some egg labels claim that the hens that produced the eggs were "humanely treated." Such a representation could be grounds for mandating more complete disclosure regarding the actual production method—for example, whether the hens were confined in open pastures or windowless sheds. Furthermore, the representations made need not be statements, but could also be "suggested by…word, design, device, or any combination thereof."[50] If the design of the labeling, for example, includes pictures of hens roaming through green pastures, such a representation could be the basis for required disclosure of production method. FDA could argue that such labeling is misleading because it fails to reveal a fact—the production method—that is material based on the label's representations—pictures of hens roaming through green pastures.

[49] Food, Drug, and Cosmetic Act, §201(n), 21 U.S.C. §343.

[50] *Id.*

Again, it would still be necessary to ensure that the food producers defined these production method claims in way that is not "false or misleading." As discussed above, consumers who purchase "cage free" eggs believe that the hens that produced the eggs were treated humanely. Currently, that is not the case, making that production method claim misleading (as it is used today). Even if FDA mandated production method claims for certain foods under §201(n), for example, the agency must also ensure that the claims are not themselves misleading. Mandating production method claims for certain foods is preferable, therefore, both because it requires giving consumers this information and because it would enable FDA to make regulations defining the production method claims to ensure that they are not misleading.

Failure to reveal facts material with respect to consequences of the use of the product

Labeling can also be deemed misleading if it "fails to reveal facts…material with respect to consequences which may result from the use" of the food "under the conditions of use prescribed in the labeling…or under such conditions of use as are customary or usual."[51] Two more recent cases discuss this prong of §201(n) in the context of labeling of products derived from cows treated with growth hormones[52] and labeling of genetically engineered foods,[53] both of which represent production methods. Unlike *American Frozen Food Institute*, in these cases the courts upheld FDA's decision to not require labeling of products that rely on these production methods. In another departure from the principles of *American Frozen Food*

[51] *Id.*

[52] Stauber v. Shalala, 895 F.Supp. 1178 (W.D.Wis.1995), holding that FDA did not act arbitrarily or capriciously on not requiring labeling of products derived from drug-treated cows.

[53] Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166 (D.C.2000), holding that the failure of FDA to require labeling for genetically engineered foods was not arbitrary or capricious, despite widespread consumer interest.

Institute, both *Stauber* and *Alliance for Bio-Integrity* reject that labeling can be mandated based solely on consumer interest. Despite that these cases preclude mandated production method claims based on consumer interest, a different interpretation of this prong of §201(n) might enable FDA to require production method claims based on other concerns.

In *Stauber v. Shalala*, consumers argued that there were organoleptic differences (i.e., differences "capable of being detected by a human sense organ") between products derived from cows treated with synthetic bovine growth hormone and untreated cows—and that this fact was material, thus requiring labeling on products from treated cows. The court agreed that labels must disclose differences in "performance characteristics"—such as organoleptic differences—because, under §201(n), it "bears on the consequence of the use of the article" and is, therefore, "material."[54] Despite this, the court found that FDA had not acted outside its discretion in refusing to require labeling for products derived from treated cows because there was inadequate evidence of such differences in "performance characteristics."[55]

The consumers urged that widespread consumer demand for labeling products derived from treated cows is also a "material fact" that should compel FDA to require such labeling. Both FDA and the court rejected this argument. The court held that consumer opinion was insufficient to compel labeling; "a factual predicate to the requirement of labeling," the court explained, "is a determination that a product differs materially from the type of product it purports to be."[56] Thus, FDA must first find that the product itself differs materially—only then can it take into account consumer desire for the labeling. Moreover, if there is no material

[54] *See* Stauber v. Shalala, 895 F.Supp. 1178, 1192-1193 (W.D.Wis.1995).

[55] *Id*. at 1193.

[56] *Id*.

difference between products derived from treated and untreated cows, then labeling them as different would itself violate the misbranding provision. Thus, absent a material difference, using consumer demand to compel labeling would violate the FD&C Act.[57]

The position of both FDA and the court in *Stauber* differs markedly from that in *American Frozen Food Institute*. *Stauber* limits FDA authority to mandate labeling by diminishing the importance of consumer interest and circumscribing the meaning of "materiality." While *American Frozen Food Institute* relied upon the importance of consumer desire for labeling and the ability of consumers to make informed comparative purchasing decisions,[58] *Stauber* rejects relying on consumer opinion absent a difference in the product.[59] Of course, consumers are interested in percentage of ingredient-labeling for seafood cocktails because some brands might have a higher percentage than others—and this is a difference in the food product itself, just as *Stauber* focused on differences in milk products. Despite this, it seems that FDA has significantly changed its position as to the importance of consumer demand for labeling in *Stauber*. Furthermore, in *American Frozen Food Institute*, the consumer desire seemed to create the materiality on which the labeling requirement depended. In contrast, *Stauber* limits the notion of materiality only to actual differences in the product itself, regardless of how consumers might perceive the product.

Alliance for Bio-Integrity relied on *Stauber*'s trivialization of consumer opinion in holding that FDA did not act arbitrarily or capriciously in failing to require labeling of

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[57] *Id*. ("In the absence of evidence of a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.")

[58] American Frozen Food Institute v. Mathews, 413 F.Supp. 548, 554 (D.C.1976).

[59] Stauber v. Shalala, 895 F.Supp. 1178, 1193 (W.D.Wis.1995).

genetically-engineered foods.[60] The court held that FDA's reading of the FD&C Act as not authorizing labeling requirements based solely on consumer demand constitutes a reasonable interpretation of the statute.[61] This holding suggests, however, that FDA could also reasonably interpret §201(n) differently, perhaps including consumer demand as a more important element in determining materiality (as the agency seemed to do with regard to percentage of ingredient-labeling in *American Frozen Food Institute*). Indeed, the court noted that—because Congress did not address whether materiality applies only to safety concerns or whether it also includes consumer interest—FDA has discretion to determine the meaning of materiality.[62] It is conceivable that FDA could interpret this provision to take into account not only consumer opinion, but also considerations about the ethical implications of food production methods (such as impacts on animal welfare or the environment). Indeed, in the context of production method claims, material differences in the food itself seem not to apply at all—the concern is not that the eggs themselves are different, but that the way the hens were confined is important as well.

The plaintiffs in *Alliance for Bio-Integrity* also argued that the *process* of genetic modification was itself a "material fact" that required labeling disclosure.[63] Because FDA had determined there were no safety concerns related to genetic medication, however, the court believed it had little basis on which to determine that the agency's interpretation of its statute

[60] Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166, 178-179 (D.C.2000)

[61] *Id.* at 179. The court noted that no "material change" had occurred in the foods at issue, and that FDA had not interpreted §201(n) to authorize mandatory food labeling "[a]bsent unique risks to consumer health or uniform changes to food derived through rDNA technology."

[62] *Id.* at 178.

[63] *Id.* at 179.

was arbitrary and capricious. The court also referred to a 1924 case that denies the materiality of methods of production "[w]hen considered independently of the product."[64] While this seems to preclude any mandatory production method labeling, the court relied on FDA's broad discretion in determining that it had not overstepped its authority. Thus, FDA could conceivably re-interpret §201(n) to take into account more factors when determining materiality. Further, the case the court mentioned was decided before the current FD&C Act was even passed, thus calling into question its applicability—particularly if it contradicts an FDA interpretation of its own statute.

While *Stauber* and *Alliance for Bio-Integrity* suggest that mandatory labeling of production methods may be difficult to impose under the FD&C Act's misbranding provision, the courts in those cases relied heavily on FDA discretion to interpret the provision. This implies that courts would also defer to FDA discretion if the agency broadened its interpretation of materiality, thereby allowing considerations such as consumer opinion, animal welfare, and environmental consequences to be taken into account. The FDA itself has noted that it has required labeling under §201(n)—on the basis of that information being "material"—when the absence of the information might "pose special health *or environmental* risks" (emphasis added).[65] Thus, FDA could determine that a product is misbranded under §201(n)—due to its "fail[ure] to reveal facts…material with respect to consequences which may result from the use" of the product[66]—not only if there are consequences to human health and safety, but also if there

[64] *Id*., quoting U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 445 (1924).

[65] Food and Drug Administration, "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance." January 2001.

[66] Food, Drug, and Cosmetic Act, §201(n), 21 U.S.C. §343.

are consequences to the environment or animal welfare. "Consequences" certainly need not refer only to health and safety, and the ethical implications of our food choices could be said to result from "the use" of the food products we consume.

Conclusion

Food labels on products from eggs to ice cream make clear that today's consumers are concerned with the ethical implications of what we eat. We care not just about the health and safety of our foods, but also whether the animals used in their production were treated humanely and what environmental consequences result. Food producers capitalize on these concerns with labels such as "cage free" and "free range." And because consumers are willing to pay more for products that are consistent with their ethical sensibilities, food producers can charge more by adding production method claims to their labels. Despite this, there is little to no regulation of production method claims by either FDA or USDA.

Congress could pass legislation authorizing FDA or USDA to regulate production method claims, just as it expanded FDA's jurisdiction over disease prevention and nutrient content claims through the Nutrition Labeling and Education Act of 1990. However, even without new legislation, the agencies could regulate production method claims under the misbranding provisions of the FD&C Act and FMIA. Under these provisions, they could regulate voluntarily-made production method claims that are deemed "false or misleading." Furthermore, FDA may be able to mandate production method labeling in circumstances in which the production method is determined to be "material," thus making labels that fail to disclose this information misleading. Although there are many challenges to using the misbranding provision to regulate production method claims, the consequences of our food choices are too important to ignore.